

STARK STATEMENT INTRODUCING THE PhRMA ACT

Tuesday, 15 February 2005

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Mr. Speaker,

People are dying because the drug industry is making billions marketing drugs they know to be unsafe. Today I propose a bill that will end this

dangerous practice by increasing accountability for pharmaceutical manufacturers and their executives who withhold evidence of drug risks.

The Pharmaceutical Research and Manufacturers Accountability (PhRMA) Act would impose criminal penalties and fines on those who fail to disclose evidence of serious adverse drug experiences. It is unfortunate we need this legislation, but the only way to make manufacturers accountable for drug safety is to hit them where it hurts — putting executives in jail and imposing large individual and corporate fines for wrongdoing.

In the past 6 months alone, Vioxx has been taken off the market for causing heart attacks and strokes, and a new “black box” warning has been added to antidepressants due to increased risk of suicide in children. What’s worse, evidence suggests the manufacturers knew about these deadly safety issues, but masked or withheld the information from consumers and the FDA because they were making so much money on these drugs.

Profit before public safety is the modern mantra of pharmaceutical manufacturers. These companies continued to market drugs that caused individuals to be severely physically disabled or die. While the companies have been civilly sued for their actions, their typical response has been to pay enormous monetary settlements that don’t even put a dent in their outrageously high drug profits. Even worse, the manufacturers never admit guilt and require injured parties to sign non-disclosure agreements as part of the settlement, effectively hiding from the public the horrific tales of death and disability.

The PhRMA Act will put an end to this irresponsible corporate citizenship by placing responsibility for the knowing concealment of serious adverse drug experiences on the pharmaceutical executives who ultimately decide to place profits over people’s lives. In the wake of Enron and other corporate accounting scandals, the Sarbanes-Oxley Act created 10-year prison terms for withholding financial information from shareholders and regulators. The PhRMA Act would impose a minimum jail term of 20 years and fines of up to \$2 million on executives who withhold information, proving once and for all that life is more valuable than the almighty dollar.

The bill would also require CEOs to annually attest that they have disclosed all evidence of serious adverse drug experiences to the FDA. Failure to meet this requirement would result in fines up to \$100,000 per month for the CEO and \$1 million per month for the Corporation.

Under today's fast track process at FDA, drugs are often approved with the caveat that manufacturers complete specified post-marketing studies of safety and effectiveness. Unfortunately, drug companies currently ignore these requirements because they know FDA will not revoke approval of a drug unless it is clearly unsafe. This perverse system actually provides an incentive for manufacturers to ignore required post-marketing studies so there is no new safety evidence available for FDA to justify a market withdrawal.

The PhRMA Act ameliorates this problem by requiring post-marketing studies to be completed in a time-period specified by the FDA. Failure to complete these studies can lead to fines of \$5 million for each month the study goes unfinished. As always, FDA retains the authority to pull a drug from the market, but the PhRMA Act would give them an important intermediate sanction to make drug companies accountable for meeting their obligations.

The influence of the drug industry has infiltrated every aspect of society. The Bush Administration gave drug manufacturers a huge windfall in the Medicare prescription drug bill, the FDA bows to the industry while ignoring the science, and millions are taking unnecessary prescriptions because of TV commercials or doctors bribed by manufacturers.

The PhRMA Act can begin to turn the tide on an industry that continually puts profit and shareholder earnings above patients' lives and health. By holding pharmaceutical manufacturers and their executives responsible for the safety of their products we can ensure prescription drugs save lives, not destroy them.